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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/806,795 | 04/04/2001 | Staffan Folestad | 1103326-0660 | 6487 |

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

TSOY, ELENA

ART UNIT PAPER NUMBER

1762

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,795

Applicant(s)

FOLESTAD ET AL.

Examiner

Elena Tsoy

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-20,22-25 and 27-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-20,22-25 and 27-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1, 2, 7-9, 13-18, 20, 22-25, 27, 31, 32, 37-39, 41, 47, 48, 53** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996) for the reasons of record as set forth in Paragraph No. 3 of the Office Action mailed on July 23, 2004.

3. **Claims 4-6, 28-30, 35, 36** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391) for the reasons of record as set forth in Paragraph No. 4 of the Office Action mailed on July 23, 2004.

4. **Claims 10, 33, 42-44, 50** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Cody (US

Art Unit: 1762

5,420,681) for the reasons of record as set forth in Paragraph No. 5 of the Office Action mailed on July 23, 2004.

5. **Claims 11, 45** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Maguire et al (US 6,038,525) for the reasons of record as set forth in Paragraph No. 6 of the Office Action mailed on July 23, 2004.

6. **Claims 12, 34, 46, 52** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391), and further in view of Patel et al (US 6,248,363) for the reasons of record as set forth in Paragraph No. 7 of the Office Action mailed on July 23, 2004.

7. **Claims 19, 40** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Woodruff (US 5,420,681) for the reasons of record as set forth in Paragraph No. 8 of the Office Action mailed on July 23, 2004.

8. **Claims 49, 51** stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 13-15, 17, 20 of U.S. Patent No. 6,633,792 in view of Drennen, III et al (US 5,750,996), further in view of Van Laethem (US 4,125,391), and further in view of Cody (US 5,420,681) for the reasons of record as set forth in Paragraph No. 9 of the Office Action mailed on July 23, 2004.

Response to Arguments

9. Applicants' arguments filed September 30, 2004 have been fully considered but they are not persuasive.

Applicants argue that the claimed invention is not an obvious variant of Folestad in light of Drennen. As acknowledged by the Examiner, Folestad fails to teach the performance of a spectrometric measurement of a single pharmaceutical particle while the *same* particle is coated within a fluidized bed. Similarly, Drennen does not disclose or suggest the performance of a spectrometric measurement of a single pharmaceutical particle while the *same* particle is coated within a fluidized bed. Drennen discloses the coating of particles within a fluidized bed and measurement of the coated particle in a probe, within or withdrawn from the fluidized bed while the coated particle is trapped in a recess of the probe and no longer fluidized on an upwardly directed gas flow.

The Examiner respectfully disagrees with this argument.

Folestad teaches that a spectrometric measurement of coating on a pharmaceutical product can be carried out on a sample within (any) coating vessel **during the actual coating** process (See Claim 10). Folestad fails to teach that *the actual coating* process of the pharmaceutical product is carried out in a fluidized bed. Drennen, III et al, on other hand, teach that a fluidized bed can be used for coating pharmaceutical product such as drug unit (particle), and a process of coating can be monitored on-line on a single particle which is fluidized on an upwardly directed flow but retrieving the particle into a probe (not while fluidized) (See Fig. 2; column 2, lines 1-5, 65-67; column 3, lines 44-48, 60-67; column 4, lines 36-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to use a method of Folestad for monitoring coating on a particle in a fluidized bed of Drennen, III et al by performing a spectrometric measurement of coating on a sample of a pharmaceutical product within the fluidized bed **during the actual coating** process instead of retrieving the particle into a probe, with the expectation of providing fast and accurate control of the coating process.

One of ordinary skill in the art at would have **reasonable expectation of success** in using the method of Folestad for monitoring a coating process of Drennen, III et al on a single particle *while it is fluidized* without retrieving the particle into a probe since Folestad teaches that a spectrometric measurement of coating on a pharmaceutical product can be carried out on a sample within (any) coating vessel **during the actual coating** process.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1762

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELENA TSOY
PRIMARY EXAMINER
ETsoy

Elena Tsoy
Primary Examiner
Art Unit 1762

November 2, 2004